IN THE CLAIMS:

Status of Claims:

1.-44. (Canceled)

45. (Previously presented) A composition of a stable, sterile, and injectable aqueous dispersion of a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion consisting essentially of

(a) between about 1% to about 15% of propofol;

(b) between about 1% to about 8% of a propofol-soluble diluent;

(c) between about 0.5% to about 5% of a surface stabilizing amphiphilic agent; and

(d) a pharmaceutically acceptable water-soluble polyhydroxy additive that acts as a tonicity modifier; and

(e) water;

(f) provided the ratio of propofol to diluent is about 1:4 to about 1:0.1 and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5, and the composition has a viscosity of from about 0.8 to about 15 centipoise,

wherein the dispersion

prevents microbial growth, defined as no more than 0.5 log increase from the initial inoculum, of each of *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Candida albicans,* and *Aspergillus niger* for at least 7 days as measured by a test wherein a washed suspension of each said organism is added to a separate aliquot of said dispersion at approximately 1000 colony forming units per mL, at a temperature in the range 20-25°C, whereafter said aliquots are incubated at 20-25°C and are tested for viability of the microorganisms in the inoculated dispersion as determined by counting the colonies of said organism after 24, 48 hours and 7 days; and

results in no irritation at the site of injection as evidenced by a test wherein said dispersion is administered as a single daily bolus injection of 12.5 mg/kg, given on the basis of body weight, for 2 successive days over a period of approximately 30 seconds, in the caudal vein of a rat such that no visual increase in the diameter of the rat tail is noted after 48 hours post injection.

46. (Previously presented) The composition of claim 45, wherein the surface stabilizing agent is a surface modifier selected from the group consisting of ionizable phospholipid, non-ionizable phospholipid, a mixture of ionizable phospholipid and cholesterol, a mixture of non-ionizable phospholipid and cholesterol, and mixtures thereof.

47. (Previously presented) The composition of claim 45, wherein the propofol-soluble diluent is selected from the group consisting of a synthetic fatty acid triglyceride, a natural fatty acid triglyceride, and mixtures thereof.

48. (Previously presented) The composition of claim 45, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:3 to about 1:0.5.

49. (Previously presented) The composition of claim 45, wherein the ratio of propofol to the propofol-soluble diluent is from about 1:2 to about 1:1.

50. (Previously presented) The composition of claim 45, wherein the propofol-soluble diluent is a mixture of medium-chain triglyceride and vegetable oil.

51. (Previously presented) The composition of claim 50, wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.

52. (Previously presented) The composition of claim 45, wherein the composition contains about 2% to about 10% of propofol.

53. (Previously presented) The composition of claim 45, wherein the pharmaceutically acceptable water-soluble polyhydroxy additive provides the propofol-containing dispersion or composition with an osmolality of about 250 to about 700 milliosmolal.

54. (Previously presented) The composition of claim 53, wherein the osmolality is about 300 to about 500 milliosmolal.

55. (Previously presented) The composition of claim 45, wherein the viscosity is from about 2 to about 5 centipoise.

56. (Previously presented) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix of mean diameter from about 50 nm to about 1000 nm, the dispersion being capable of inhibiting the growth of microorganisms and consisting essentially of about 1% to about 15% of propofol, up to about 7% of a propofol-soluble diluent, and about 0.8% to about 4% of a surface stabilizing amphiphilic agent, water, and a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier, the dispersion being devoid of additional bactericidal or bacteriostatic preservative agents and causing no irritation at the site of injection.

57. (Previously presented) The dispersion of claim 56, wherein the propofol and diluent are present in a ratio of about 1:4 to about 1:0.1 of propofol to diluent.

58. (Previously presented) The dispersion of claim 56, where the propofol and amphiphilic agent are present in a ratio of about 1:0.8 to about 1:2.5 of propofol to amphiphilic agent.

59. (Previously presented) The dispersion of claim 56, that has a viscosity of from about 0.8 to about 15 centipoise.

60. (Previously presented) The dispersion of claim 56, wherein the propofol-soluble diluent is selected from the group consisting of a pharmaceutically acceptable saturated fatty acid triglyceride, a pharmaceutically acceptable unsaturated fatty acid triglyceride, and mixtures thereof.

61. (Previously presented) The dispersion of claim 56, wherein the propofol-soluble diluent is selected from the group consisting of pharmaceutically acceptable esters of medium chain fatty acids, pharmaceutically acceptable esters of long chain fatty acids, pharmaceutically acceptable triglycerides of medium chain fatty acids, and mixtures thereof.

62. (Previously presented) The dispersion of claim 56, wherein the propofol-soluble diluent is selected from the group consisting of isopropyl myristate, cholesteryl oleate, ethyl oleate, squalene, alpha-tocopherol, and mixtures thereof.

63. (Previously presented) The dispersion of claim 56, wherein the propofol-soluble diluent is a mixture of medium chain triglyceride and vegetable oil.

64. (Previously presented) The dispersion of claim 63, wherein the ratio of medium-chain triglyceride to vegetable oil is from 1:3 to 3:1.

65. (Previously presented) The dispersion of claim 56, which contains about 2% to about 10% of propofol.

66. (Previously presented) The dispersion of claim 56, wherein the surface stabilizing amphiphilic agent is a surface modifier selected from the group consisting of ionizable phospholipid, non-ionizable phospholipid, a mixture of ionizable phospholipid and cholesterol, a mixture of non-ionizable phospholipid and cholesterol, and mixtures thereof.

67. (Previously presented) The dispersion of claim 56, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of charged phospholipid of natural sources, uncharged phospholipid of natural sources, hydrogenated lecithin, a synthetic phospholipid, a poloxamer, a poloxamine, a polyoxyethylene sorbitan ester, and mixtures thereof.

68. (Previously presented) The dispersion of claim 56, wherein the surface stabilizing amphiphilic agent is a combination of cholesterol and one or more charged or uncharged phospholipid of natural sources, hydrogenated lecithin, or synthetic phospholipids.

69. (Previously presented) The dispersion of claim 56, wherein the surface stabilizing amphiphilic agent is selected from the group consisting of 1 ,2-dimyristoyl-sn-glycero-3-phosphatidylcholine, 1 ,2-dimyristoyl-sn-glycero-3-[phospho-rac-(1 -glycerol)J, egg lecithin, egg phosphatidylcholine, soy phosphatidyicholine, saturated soy phosphatidylcholine, soy lecithin, dimyristoylphosphatidylcholine, and dimyristoylphosphatidylglycerol.

70. (Previously presented) The dispersion of claim 56 that elicits an anesthetic effect in a warm-blooded animal and human subject upon intravenous administration.

71. (Previously presented) The dispersion of claim 56, wherein the tonicity modifier is selected from the group consisting of sucrose, dextrose, trehalose, mannitol, lactose, glycerol, and mixtures thereof.

72. (Previously presented) The dispersion of claim 56 that is isotonic with blood.

73. (Previously presented) The dispersion of claim 56 that is unsuitable for intravenous injection.

74. (Previously presented) The dispersion of claim 56 that contains a pharmaceutically acceptable water-soluble polyhydroxy tonicity modifier in an amount so as to provide an osmolality of about 250 to about 700 milliosmolal.

75. (Previously presented) The dispersion of claim 74, wherein the osmolality is about 300 to about 500 milliosmolal.

76. (Previously presented) The dispersion of claim 56 that has a viscosity from about 2 to about 5 centipoise.

77. (Previously presented) The composition of claim 45, wherein propofol is present in an amount of about 2% to 5% by weight of the dispersion.

78. (Previously presented) The composition of claim 77, wherein propofol is present in an amount of about 2% by weight of the dispersion.

79. (Previously presented) The composition of claim 45, wherein the polyhydroxy additive is present in an amount of about 2.5% to about 20% by weight of the dispersion.

80. (Previously presented) The composition of claim 45, wherein the polyhydroxy additive is mannitol.

81. (Previously presented) The composition of claim 80, wherein mannitol is present in an amount of about 5.5% by weight of the dispersion.

82. (Previously presented) The composition of claim 45, wherein the propofol-soluble diluent is a medium chain triglyceride.

83. (Previously presented) The composition of claim 45, wherein the propofol-soluble diluent is a mixture of medium-chain triglycerides.

84. (Previously presented) The composition of claim 82, wherein the medium-chain triglyceride is a triglyceride of medium-chain fatty acids of synthetic or natural origin.

85. (Previously presented) The composition of claim 82, wherein the medium-chain triglyceride is present in an amount of 2% to 6% by weight of the dispersion.

86. (Previously presented) The composition of claim 85, wherein the medium-chain triglyceride is present in an amount of 2% to 4% by weight of the dispersion.

87. (Previously presented) The composition of claim 86, wherein the medium-chain triglyceride is present in an amount of 4% by weight of the dispersion.

88. (Previously presented) The composition of claim 83, wherein the mixture of medium-chain triglycerides is present in an amount of 4% by weight of the dispersion.

89. (Previously presented) The composition of claim 45, wherein the amphiphilic agent is egg lecithin.

90. (Previously presented) The composition of claim 89, wherein the egg lecithin is present in an amount of about 1% to about 7% by weight of the dispersion.

91. (Previously presented) The composition of claim 90, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion.

92. (Previously presented) The composition of claim 91, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion.

93. (Previously presented) The composition of claim 89, wherein the egg lecithin contains not less than 98% phosphatidyl choline.

94. (Previously presented) The composition of claim 45, which includes anionic dimyristoylphosphatidyl glycerol.

95. (Previously presented) The composition of claim 94, wherein the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.05% to 0.25% by weight of the dispersion.

96. (Previously presented) The composition of claim 95, wherein the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

97. (Previously presented) The composition of claim 45, which includes egg lecithin and anionic dimyristoylphosphatidyl glycerol.

98. (Previously presented) The composition of claim 97, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion and the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.05% to 0.25% by weight of the dispersion.

99. (Previously presented) The composition of claim 98, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion and the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

100. (Previously presented) The composition of claim 45, wherein the pH of the composition is about 4 to about 9.

101. (Previously presented) The composition of claim 100, wherein the pH of the composition is about 5 to about 8.

102. (Previously presented) The composition of claim 45, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

103. (Previously presented) The composition of claim 45, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

104. (Previously presented) The composition of claim 102, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

105. (Previously presented) The composition according to claim 45, wherein the dispersion is steam sterilizable.

106. (Previously presented) The dispersion of claim 56, wherein propofol is present in an amount of about 2% to 5% by weight of the dispersion.

107. (Previously presented) The dispersion of claim 106, wherein propofol is present in an amount of about 2% by weight of the dispersion.

108. (Previously presented) The dispersion of claim 56, wherein the polyhydroxy tonicity modifier is present in an amount of 2.5% to about 20% by weight of the dispersion.

109. (Previously presented) The dispersion of claim 56, wherein the polyhydroxy tonicity modifier is mannitol.

110. (Previously presented) The dispersion of claim 109, wherein mannitol is present in an amount of about 5.5% by weight of the dispersion.

111. (Previously presented) The dispersion of claim 56, wherein the propofol-soluble diluent is a medium-chain triglyceride.

112. (Previously presented) The dispersion of claim 56, wherein the propofol-soluble diluent is a mixture of medium-chain triglycerides.

113. (Previously presented) The dispersion of claim 111, wherein the medium-chain triglyceride is a triglyceride of medium chain fatty acids of synthetic or natural origin.

114. (Previously presented) The dispersion of claim 111, wherein the medium-chain triglyceride is present in an amount of 2% to 6% by weight of the dispersion.

115. (Previously presented) The dispersion of claim 114, wherein the medium-chain triglyceride is present in an amount of 2% to 4% by weight of the dispersion.

116. (Previously presented) The dispersion of claim 115, wherein the medium-chain triglyceride is present in an amount of 4% by weight of the dispersion.

117. (Previously presented) The dispersion of claim 112, wherein the mixture of medium-chain triglycerides is present in an amount of 4% by weight of the dispersion.

118. (Previously presented) The dispersion of claim 56, wherein the amphiphilic agent is egg lecithin.

119. (Previously presented) The dispersion of claim 118, wherein the egg lecithin is present in an amount of about 1% to about 7% by weight of the dispersion.

120. (Previously presented) The dispersion of claim 118, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion.

121. (Previously presented) The dispersion of claim 120, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion.

122. (Previously presented) The dispersion of claim 118, wherein the egg lecithin contains not less than 98% phosphatidyl choline.

123. (Previously presented) The dispersion of claim 56, which includes anionic dimyristoylphosphatidyl glycerol.

124. (Previously presented) The dispersion of claim 123, wherein the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.05% to 0.25% by weight of the dispersion.

125. (Previously presented) The dispersion of claim 124, wherein the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

126. (Previously presented) The dispersion of claim 56, which includes egg lecithin and anionic dimyristoylphosphatidyl glycerol.

127. (Previously presented) The dispersion of claim 126, wherein the egg lecithin is present in an amount of about 1% to 3% by weight of the dispersion and the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.05% to 0.25% by weight of the dispersion.

128. (Previously presented) The dispersion of claim 127, wherein the egg lecithin is present in an amount of 1.6% by weight of the dispersion and the anionic dimyristoylphosphatidyl glycerol is present in an amount of 0.1% by weight of the dispersion.

129. (Previously presented) The dispersion of claim 56, wherein the pH of the dispersion is about 4 to about 9.

130. (Previously presented) The dispersion of claim 129, wherein the pH of the dispersion is about 5 to about 8.

131. (Previously presented) The dispersion of claim 56, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

132. (Previously presented) The dispersion of claim 56, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

133. (Previously presented) The dispersion of claim 131, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

134. (Previously presented) The dispersion of claim 56, wherein the dispersion is steam sterilizable.

135. (Previously presented) The dispersion of claim 70, wherein the anesthetic effect comprises at least one of producing and maintaining ambulatory anesthesia, neurosurgical anesthesia, pediatric anesthesia, monitored anesthetic care, intensive care sedation, chronic sedation, general anesthesia, low dose sedation, and long-term sedation.

136. (Previously presented) A composition of a stable, sterile, and injectable aqueous dispersion of a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm, the dispersion consisting essentially of:

(a) propofol in an amount from about 1% to about 15% by weight of the dispersion;

(b) a propofol-soluble diluent in an amount from about 1% to about 8% by weight of the dispersion;

(c) a surface stabilizing amphiphilic agent in an amount from about 0.5% to about 5% by weight of the dispersion;

(d) a pharmaceutically acceptable water-soluble polyhydroxy additive; and

(e) water;

(f) provided the ratio of propofol to diluent is about 1:4 to about 1:0.1 and the ratio of propofol to amphiphilic agent is about 1:0.8 to about 1:2.5 and the composition has a viscosity of about 0.8 to about 15 centipoise;

wherein the dispersion prevents microbial growth of no more than 0.5 log increase from the initial inoculum, of any one of Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, Candida albicans, and Aspergillus niger for at least 7 days as measured by a test wherein a washed suspension of the microbe is added to an aliquot of said dispersion at approximately 1000 colony forming units per mL, at a temperature in the range of 20-25°C, whereafter said aliquot is incubated at 20-25°C and tested for viability of the microbe in the inoculated dispersion as determined by counting the colonies of the microbe after 24 hours, 48 hours, and 7 days; and

wherein the dispersion results in no irritation at the site of injection as evidenced by a test wherein said dispersion is administered as a single daily bolus injection of 12.5 mg/kg, given on the basis of body weight, for 2 successive days over a period of approximately 30 seconds, in the caudal vein of a rat such that no visual increase in the diameter of the rat tail is noted after 48 hours post injection.

137. (Currently Amended) A composition of a stable, sterile and injectable aqueous dispersion of a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm, the dispersion consisting essentially of:

(a) propofol in an amount of about 2% by weight of the dispersion;

(b) one or more [[a]] medium-chain ~~triglyceride~~ triglycerides in an amount of 4% by weight of the dispersion;

(c) egg lecithin in an amount of 1.6% by weight of the dispersion;

(d) anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion;

(e) mannitol in an amount of 5.5% by weight of the dispersion; and

(f) water.

138. (Canceled)

139. (Previously presented) The composition of claim 137, wherein the medium chain triglyceride is of synthetic or natural origin.

140. (Previously presented) The composition of claim 137, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

141. (Previously presented) The composition of claim 137, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

142. (Previously presented) The composition of claim 140, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

143. (Previously presented) The composition of claim 137, wherein the dispersion is steam sterilizable.

144. (Previously presented) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm capable of inhibiting the growth of microorganisms, the dispersion consisting essentially of:

propofol in an amount of about 2% by weight of the dispersion;

a medium-chain triglyceride in an amount of 4% by weight of the dispersion;

egg lecithin in an amount of 1.6 % by weight of the dispersion;

anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion; and

mannitol in an amount of 5.5% by weight of the dispersion;

wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents and causes no irritation at the site of injection.

145. (Previously presented) An injectable, stable, sterile, and antimicrobial aqueous dispersion comprising a water-insoluble microdroplet matrix having a mean diameter of about 50 nm to about 1000 nm capable of inhibiting the growth of microorganisms, the dispersion consisting essentially of:

propofol in an amount of about 2% by weight of the dispersion;

a mixture of medium-chain triglycerides in an amount of 4% by weight of the dispersion;

egg lecithin in an amount of 1.6 % by weight of the dispersion;

anionic dimyristoylphosphatidyl glycerol in an amount of 0.1% by weight of the dispersion; and

mannitol in an amount of 5.5% by weight of the dispersion;

wherein the dispersion is devoid of additional bactericidal or bacteriostatic preservative agents and causes no irritation at the site of injection.

146. (Previously presented) The dispersion of claim 144, wherein the medium chain triglyceride is of synthetic or natural origin.

147. (Previously presented) The dispersion of claim 144, wherein the dispersion is sealed in a glass vial under nitrogen with a stopper.

148. (Previously presented) The composition of claim 144, wherein the dispersion is sealed in a glass vial under an inert atmosphere with a stopper.

149. (Previously presented) The dispersion of claim 147, wherein the dispersion is filled to about 70-90% volume capacity in the glass vial.

150. (Previously presented) The composition of claim 144, wherein the dispersion is steam sterilizable.